



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[Docket No. FDA-2021-N-1322]

Kris A. Hampton-Bey II: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debaring Kris A. Hampton-Bey II for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Hampton-Bey II engaged in a pattern of importing or offering for import misbranded drugs (i.e. in an amount, frequency, or dosage that is inconsistent with his personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA. Mr. Hampton-Bey II was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of May 8, 2022 (30 days after receipt of the notice), Mr. Hampton-Bey II had not responded. Mr. Hampton-Bey II's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM-4029), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240 402-8743, or at debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION

I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(D) of the FD&C Act, that the individual has engaged in a pattern of importing or offering for import adulterated or misbranded drugs (i.e. in an amount, frequency, or dosage that is inconsistent with personal or household use by the importer) that are not designated in an entry in an authorized electronic data interchange system as products regulated by FDA.

After an investigation, FDA discovered that Mr. Hampton-Bey II has engaged in numerous instances of importing or offering for import misbranded drugs; all the parcels containing the misbranded drugs serving as the basis for this action, described in further detail below, were intercepted by FDA at either the Newark or Chicago International Mail Facilities (IMF) and were addressed to Mr. Hampton-Bey II at an address connected to him.

On or about March 11, 2019, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Chicago IMF and which was addressed to him. FDA determined that the product contained in this parcel was 550 tablets of sildenafil citrate and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol “Rx only” on its label and because the article was determined to lack adequate directions for use. The product was refused entry on April 8, 2019.

On or about June 25, 2019, Mr. Hampton-Bey II offered for import two parcels intercepted and processed by FDA at the Chicago IMF and which were addressed to him. FDA determined that the product contained in the first parcel was 850 tablets of Sildenafil Tabs 100 MG and was a misbranded drug because the article was determined to lack adequate directions for use and because the article was determined to be a prescription drug but did not include the symbol “Rx only” on its label. FDA determined that the product contained in the second parcel

was 850 tablets of Sildenafil 100 MG Tabs and was a misbranded drug because the article was determined to lack adequate directions for use and because the article was determined to be a prescription drug but did not include the symbol “Rx only” on its label. Both products were refused entry on July 17, 2019.

On or about August 19, 2019, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Chicago IMF and which was addressed to him. FDA determined that the product contained in this parcel was 900 tablets of Sildenafil Tabs 100 MG and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol “Rx only” on its label and because the article was determined to lack adequate directions for use. The product was refused entry on September 12, 2019.

On or about December 28, 2020, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Chicago IMF and which was addressed to him. FDA determined that the product contained in this parcel was 870 tablets of Sildenafil Tabs 100 MG and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol “Rx only” on its label and because the article was determined to be a drug that was not included in a list required by section 510(j) of the FD&C Act (21 U.S.C. 360(j)). The product was refused entry on January 19, 2021.

On or about December 29, 2020, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Chicago IMF and which was addressed to him. FDA determined that the product contained in this parcel was 870 tablets of sildenafil citrate and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol “Rx only” on its label. The product was refused entry on January 21, 2021.

On or about December 29, 2020, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Chicago IMF and which was addressed to him. FDA determined that the product contained in this parcel was 870 tablets of sildenafil citrate and was a

misbranded drug because the article was determined to lack adequate directions for use. The product was refused entry on January 22, 2021.

On or about January 5, 2021, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Chicago IMF and which was addressed to him. FDA determined that the product contained in this parcel was 870 tablets of sildenafil and was a misbranded drug because the article was determined to lack adequate directions for use and because the article was determined to be a prescription drug but did not include the symbol “Rx only” on its label. The product was refused entry on February 5, 2021.

On or about January 6, 2021, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Chicago IMF and which was addressed to him. FDA determined that the product contained in this parcel was 870 tablets of Sildenafil Tablets 100 MG and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol “Rx only” on its label and because the article had been determined to lack adequate directions for use. The product was refused entry on February 1, 2021.

On or about January 7, 2021, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Chicago IMF and which was addressed to him. FDA determined that the first product contained in this parcel was 850 tablets of sildenafil citrate and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol “Rx only” on its label and because the article had been determined to lack adequate directions for use. FDA determined that the second product contained in this parcel was 10 tablets of sildenafil citrate tablets and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol “Rx only” on its label and because the article had been determined to lack adequate directions for use. Both products were refused entry on February 3, 2021.

On or about March 4, 2021, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Chicago IMF and which was addressed to him. FDA determined

that the product contained in this parcel was 87 tablets of sildenafil tablets and was a misbranded drug because the article was determined: (1) to be a prescription drug but did not include the symbol “Rx only” on its label; (2) not to bear a label containing the name and place of business of the manufacturer, packer, or distributor; (3) to be a drug that was not included in a list required by section 510(j) of the FD&C Act; and (4) to be a drug that was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 of the FD&C Act. The product was refused entry on April 5, 2021.

On or about March 17, 2021, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Newark IMF and which was addressed to him. FDA determined that the product contained in this parcel was 364 tablets of BEGMA-100 Sildenafil Citrate Tablets 100 MG and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol “Rx only” on its label. The product was refused entry on April 23, 2021.

On or about March 24, 2021, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Chicago IMF and which was addressed to him. FDA determined that the product contained in this parcel was 870 tablets of sildenafil citrate and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol “Rx only” on its label. The product was refused entry on April 19, 2021.

On or about April 20, 2021, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Chicago IMF and which was addressed to him. FDA determined that the product contained in this parcel was 800 tablets of Sildenafil 100 MG Tablets and was a misbranded drug because the article was determined to be a drug that was not included in a list required by section 510(j) of the FD&C Act. The product was refused entry on May 11, 2021.

As a result of this pattern of importing or offering for import misbranded drugs (i.e. in an amount, frequency, or dosage that is inconsistent with his personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA, in

accordance with section 306(b)(3)(D) of the FD&C Act, FDA sent Mr. Hampton-Bey II, by certified mail on April 4, 2022, a notice proposing to debar him for a 5-year period from importing or offering for import any drug into the United States.

In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Hampton-Bey II's pattern of conduct and concluded that his conduct warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Hampton-Bey II of the proposed debarment and offered him an opportunity to request a hearing, providing 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Hampton-Bey II received the proposal and notice of opportunity for a hearing on April 8, 2022. Mr. Hampton-Bey II failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(D) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Kris A. Hampton-Bey II has engaged in a pattern of importing or offering for import misbranded drugs (i.e. in an amount, frequency, or dosage that is inconsistent with his personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA. FDA finds that this pattern of conduct should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Hampton-Bey II is debarred for a period of 5 years from importing or offering for import any drug into the United States, applicable (see

DATES). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Hampton-Bey II is a prohibited act.

Any application by Mr. Hampton-Bey II for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2021-N-1322 and sent to the Dockets Management Staff (see ADDRESSES). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at <http://www.regulations.gov> or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: July 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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